IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 16-129-LPS-SRF
	)	
WATSON LABORATORIES, INC.,	)	**UNDER SEAL**
	)	
Defendant.	)	

REPORT AND RECOMMENDATION

I. INTRODUCTION

In this Hatch-Waxman action filed by plaintiff Alcon Research, Ltd. ("Alcon") against defendant Watson Laboratories, Inc. ("Watson"), Alcon alleges infringement of United States Patent Nos. 7,947,295 ("the '295 patent"), 8,921,337 ("the '337 patent"), and 9,662,398 ("the '398 patent") (collectively, the "asserted patents" or the "patents-in-suit"). Presently before the court is the matter of claim construction regarding the '398 patent.[1] This order sets forth the court's recommendations of constructions for the disputed claim terms discussed in the briefing and at the *Markman* hearing held on November 1, 2017.

II. BACKGROUND

A. The Parties

Alcon is a Delaware corporation with its headquarters in Fort Worth, Texas. (D.I. 107 at ¶ 4) Alcon manufactures and sells the drug product known as Ilevro®, an FDA-approved

[1] As explained in greater detail at § II.B, *infra*, the court previously held a *Markman* hearing on January 13, 2017 and issued a Report and Recommendation on February 15, 2017 regarding the disputed claim terms in the '295 and '337 patents. (D.I. 58) On May 30, 2017, the '398 patent issued to Alcon. (D.I. 106) This Report and Recommendation is limited to disputed claim terms in the recently-added '398 patent.

ophthalmic suspension for topical administration to the eye containing the active pharmaceutical ingredient ("API") nepafenac. (*Id.* at ¶ 18) Alcon is also the owner by assignment of the patents-in-suit. (*Id.* at ¶¶ 19-21)

Watson is a Nevada corporation having a place of business in Corona, California, and a place of business in Parsippany, New Jersey. (*Id.* at ¶ 5) Watson is in the business of manufacturing and selling generic versions of branded pharmaceutical products for the United States market. (*Id.*)

B. Procedural Posture

This case arises out of Watson's submission of Abbreviated New Drug Application ("ANDA") No. 208816 to the United States Food and Drug Administration ("FDA"), which seeks approval to market a generic version of Alcon's Ilevro® nepafenac ophthalmic suspension. (D.I. 107 at ¶¶ 1-2) Alcon is the assignee of the patents-in-suit, which are listed in the Orange Book in connection with Ilevro®. (*Id.* at ¶¶ 19-21)

Alcon filed suit against Watson on March 4, 2016, alleging that Watson's submission of ANDA No. 208816 infringes the '295 and '337 patents. (D.I. 1 at ¶ 8) On June 30, 2016, this action was referred by Judge Robinson for discovery and all motions to dismiss, amend, transfer, and any discovery motions permitted. The case was reassigned to Chief Judge Stark on December 21, 2016. Chief Judge Stark referred the case to the undersigned magistrate judge for all purposes through case-dispositive motions, including claim construction. (D.I. 50) The parties completed briefing on claim construction of the '295 and '337 patents on December 30, 2016. (D.I. 39; D.I. 44; D.I. 46; D.I. 49) A *Markman* hearing was held on January 13, 2017. (D.I. 55) On February 15, 2017, the court issued a Report and Recommendation on the

construction of the disputed terms in the '295 and '337 patents, which was adopted on November 9, 2017. (D.I. 58; D.I. 147)

On May 30, 2017, the '398 patent issued to Alcon. (D.I. 106) On June 14, 2017, the parties filed a stipulation and proposed order to amend the case schedule and to file an amended complaint. (D.I. 106) On June 26, 2017, Alcon filed its amended complaint, adding the '398 patent to the present action. (D.I. 107) The '295 patent claims pharmaceutical compositions that are commercialized by Alcon under the trade name Ilevro® for the treatment of pain and inflammation associated with cataract surgery. (D.I. 1 at ¶ 24)

C. The '398 Patent

The '398 patent, entitled "Carboxylvinyl Polymer-Containing Nanoparticle Suspensions," is listed in connection with Ilevro® in the Orange Book. (D.I. 106) The '398 patent is a continuation of the '337 patent. (*Id.*) Watson submitted an amendment to ANDA No. 208816 to the FDA, seeking approval to engage in the commercial manufacture, use, and/or sale of Watson's ANDA product in the United States before the expiration of the '398 patent. (*Id.*)

The '398 patent claims ophthalmic compositions that are particularly suitable for delivering sparingly soluble pharmaceutical compounds, including nepafenac, into the eye. ('398 patent, col. 1:29-34) The composition of nanoparticles are suspended in a vehicle comprising a carboxyvinyl polymer, a galactomannan, and borate to stabilize the viscosity, thereby increasing the bioavailability of the drug. (*Id.* at col. 1:18-21) The inventive compositions are pharmacologically superior to the compositions previously known in the art because they form a gel when applied to the eye due to chemical interactions between the galactomannan and the borate when they come into contact with the slightly higher pH of the

eye. (*Id.* at col. 2:54-61) This allows the drug to penetrate the eye tissue without being diluted or flushed from the eye by the tear film. (*Id.* at col. 1:32-34)

III. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). However, subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015).

In construing the claims, the court should look first and foremost to the words of the claims themselves, which "are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted); *see also Eon Corp. IP Holdings v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016). Claim terms are typically used consistently throughout the patent, and "usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Phillips*, 415 F.3d at 1314 (observing that "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . .").

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a

presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003) (citing *Ecolab Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1375 (Fed. Cir. 2002).

Other intrinsic evidence, including the patent specification, "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007). The specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. The prosecution history, which is also "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent

and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

A court also may rely on "extrinsic evidence," which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* ("[C]onclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court."). Overall, while extrinsic evidence may be useful to the court, it is less reliable than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19.

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction."

Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

IV. CONSTRUCTION OF DISPUTED TERMS

A. Term 1: "native guar" ('398 patent, claims 1, 13-14, 21, 32)

Alcon	Watson	Court
"naturally occurring guar, including such guar which has been processed to make it suitable for ophthalmic pharmaceutical use"	Indefinite; but if the Court finds this term is not indefinite, Watson proposes the following construction: "A galactomannan that is not guar or hydroxypropyl guar, that is exemplified by USP or general grade native guar powder sold by TIC Gums, Inc. in December 2009"	Indefinite

I recommend that the court find the term "native guar" indefinite.[2] The Supreme Court has held that "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). The intrinsic record in the present case fails to inform a person of ordinary skill in the art about the objective boundaries of the term "native guar."

The parties agree that the term "native guar" has no plain and ordinary meaning to one of ordinary skill in the art. (11/1/17 Tr. at 5:19-23, 26:4-11) Moreover, "native guar" is not expressly defined in the specification. Instead, the specification provides the following guidance regarding the meaning of the disputed term:

> Preferred galactomannans of the present invention are guar, native guar, and hydroxypropyl guar. In a preferred embodiment of the present invention, native

[2] If the court adopts the recommendation of indefiniteness with respect to "native guar," there is no need to proceed with the construction of the remaining two terms.

> guar is present at a concentration of about 0.2 w/v %. Native guar is particularly preferred, for example, USP or general grade native guar powder obtained from TIC Gums, Inc. A process for producing a particularly preferred native guar is disclosed in co-pending U.S. patent application Ser. No. 12/701,339, entitled "Process for Purifying Guar" filed Feb. 5, 2010.

('398 patent, col. 4:21-30)

Alcon alleges that native guar is naturally occurring guar which is not chemically modified, relying on the dictionary definition of "native" as "occurring in nature esp. uncombined with other elements" or "as found in nature." (11/1/17 Tr. at 8:10-9:6; D.I. 128, Ex. F) However, Alcon blurs the distinction between native and synthetic guars by declaring that "[t]here is absolutely no record evidence that 'completely man-made' guars exist." (D.I. 134 at 5) Alcon's proposed construction thus permits native guar to undergo processing which alters its naturally-occurring condition, while simultaneously acknowledging that synthetic guars must have naturally-occurring components. Further adding to the ambiguity of the term, Alcon states that "[a] substance can be 'naturally occurring' even if on rare occasions it can also be mimicked synthetically." (D.I. 134 at 5) The intrinsic record does not sufficiently identify the properties a naturally-occurring native guar possesses to distinguish it from a synthetic version mimicking the native substance.

The purification process referenced in the '398 patent specification and described in U.S. patent application 12/701,339 ("the '339 application") seemingly contradicts Alcon's arguments in support of its construction requiring native guar to be "naturally occurring." The '339 application describes the combination of guar with borate in an aqueous solution, resulting in the chemical modification of the guar as the "guar forms an anionic polyelectrolyte polymer with borate," resulting in guar with "desirable viscosity and solution transmission properties [that] hydrates quickly in solution, and has an improved purity profile." (D.I. 128, Ex. B at Ex. 16 at

[0011]) This chemical modification is consistent with the '398 patent specification, which explains that "the compositions of the present invention utilize a galactomannan-borate system in aqueous solution. A borate anion will condense onto the cis-diol groups of a galactomannan molecule, and may cross-link with a second galactomannan molecule." ('398 patent, col. 3:47-51) Thus, the intrinsic record supports the notion that "native guar" may include chemically modified galactomannans, thereby contradicting the "naturally occurring" language proposed by Alcon.

Alcon relies on the Federal Circuit's decision in *Amgen Inc. v. F. Hoffman-La Roche Ltd.* in support of its contention that imposing a source limitation on "native guar" does not render the asserted claims indefinite. 580 F.3d 1340, 1372-73 (Fed. Cir. 2009). In its decision, the Federal Circuit concluded that the district court permissibly construed the source of the EPO as a limitation of the asserted claims and concluded that the source imparted structural and functional features distinguishing it from EPO derived from other sources. *Id.* at 1373. However, Alcon has failed to identify how the source limitation it proposes for "native guar" imparts structural or functional features sufficient to clarify its meaning to a person of ordinary skill in the art.

Given that the term "native guar" would not have an ordinary meaning to a person of ordinary skill in the art, and the '398 patent claims and specification fail to provide adequate guidance as to the structure and function of "native guar" sufficient to put the public on notice as to the scope of the claim term, I recommend that the court render the term "native guar" indefinite. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003) ("One cannot logically determine whether an accused product comes within the bounds of a claim of unascertainable scope.").

B. Term 2: "a galactomannan at a concentration of 0.1 to 0.4 w/v %, said galactomannan selected from the group consisting of guar, native guar, and hydroxypropyl guar" ('398 patent, claim 1)

Alcon	Watson	Court
"guar, native guar, or hydroxypropyl guar at a concentration of 0.1 to 0.4 w/v %"	"only one, single galactomannan that is guar or native guar or hydroxypropyl guar, and not mixtures or combinations thereof, at a concentration of 0.1 to 0.4 w/v %"	"only one, single galactomannan that is guar or native guar or hydroxypropyl guar, and not mixtures or combinations thereof, at a concentration of 0.1 to 0.4 w/v %"

I recommend that the court adopt Watson's proposed construction. The parties agree that independent claim 1 of the '398 patent contains a Markush group. (D.I. 128 at 13-14; D.I. 139 at 10) Claim 1 recites:

> 1. A topically administrable aqueous ophthalmic suspension composition comprising:
>
> a carboxyvinyl polymer at a concentration of 0.1 to 0.5 w/v %, and wherein said carboxyvinyl polymer is a carbomer;
>
> a galactomannan at a concentration of 0.1 to 0.4 w/v %, said galactomannan selected from the group consisting of guar, native guar, and hydroxypropyl guar;
>
> borate at a concentration of 0.4 to 2.0 w/v %; and
>
> a sparingly soluble particulate compound, said compound having a solubility in water at 25° C. of 0.001 to 0.1 w/v % and wherein said sparingly soluble particulate compound is nepafenac at a concentration of 0.1 to 1.0 w/v %.

('398 patent, claim 1) The Federal Circuit has held that "[a] Markush group is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B and C." *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1280 (Fed. Cir. 2003); *see also* MANUAL OF PATENT EXAMINING PROCEDURE ("MPEP") § 2173.05(h). In accordance with Federal Circuit precedent, there is a presumption

against permitting mixtures or combinations of elements identified in a Markush group in the absence of qualifying language in the claim or specification. *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1363 (Fed. Cir. 2016) ("*Abbott* held that if a Markush claim recites 'a member selected from the group consisting of A, B, and C,' the claim is presumed to permit the member to be one and only one of A, B, or C, and to exclude mixtures or combinations of A, B, and C.").

Consistent with Watson's proposed construction, there is no intrinsic evidence in the present record which suggests an intention to combine or mix elements of the Markush group. *See Abbott*, 334 F.3d at 1281 (requiring qualifying language such as "and mixtures thereof" or "at least one member of the group" to denote an intention to permit mixtures or combinations of Markush group members). The specification does not classify any galactomannans as both "guar" and "native guar," and instead describes them in distinctive terms. The specification identifies guar, native guar, and hydroxypropyl guar as preferred galactomannans, but singles out native guar as "particularly preferred" over the remaining members of the Markush group. ('398 patent, col. 4:21-26) Moreover, the prosecution history reveals that the patentee amended the claims to recite "native guar" to overcome prior art teaching "guar" compositions. (D.I. 137, Ex. 4; Ex. 5 at ¶¶ 14-15, 41) In the absence of intrinsic support, Alcon relies on extrinsic evidence in the form of its expert declaration (D.I. 128, Ex. B at ¶¶ 46-47), and the U.S. Pharmacopeia (*Id.*, Ex. B at Ex. 15), which are not sufficient to establish the propriety of mixing or combining members of the Markush group in view of the intrinsic record.

Alcon claims that the "comprising" language of claim 1 suggests the Markush group is inclusive or open-ended. However, the word "comprising" in claim 1 precedes the list of four ingredients in the ophthalmic suspension composition: a carboxyvinyl polymer, a

galactomannan, borate, and a sparingly soluble particulate compound. ('398 patent, col. 8:59-9:5) In contrast, the "consisting of" language precedes the Markush group within the claim language describing the galactomannan requirement. The "comprising" language in claim 1 does not modify the Markush group. "'Comprising' is not a weasel word with which to abrogate claim limitations." *See Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007) (quoting *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998)).

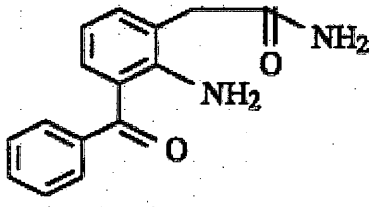
In addition, Watson's proposed construction avoids running afoul of the doctrine of claim differentiation. The claim language of dependent claim 21, which recites "[t]he composition according to claim 1 wherein said galactomannan is guar or native guar," presents two members of the Markush group as alternatives, and excludes the third member of the Markush group. ('398 patent, col. 10:11-12) Under Alcon's proposed construction, which characterizes "native guar" and "hydroxypropyl guar" as subgenera of "guar," claim 21 would be identical in scope to claim 1 because claim 21 includes "guar," and Alcon construes "hydroxypropyl guar" as being encompassed by "guar." Alcon's proposal would violate the doctrine of claim differentiation because the scope of claim 21 would be no narrower than the scope of claim 1. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004) ("[W]here the limitation that is sought to be 'read into' an independent claim already appears in a dependent claim, the doctrine of claim differentiation is at its strongest."); *see also Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1371 (Fed. Cir. 2017) ("The doctrine of claim differentiation . . . presumes that dependent claims are 'of narrower scope than the independent claims from which they depend.'" (quoting *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003)).

Alcon relies on the Federal Circuit's recent decision in *Multilayer Stretch Cling Film*

Holdings, Inc. v. Berry Plastics Corp. in support of its position because the Federal Circuit concluded that one member of the Markush group, LLDPE, encompassed another member, mLLDPE, as a subtype by its terms. 831 F.3d at 1364. However, the specification in *Multilayer* "repeatedly and consistently reference[d] blends in describing any and all resins, including the four resins of" the Markush group. *Id.* In contrast, the '398 patent specification does not reference mixtures or combinations of the Markush group elements, and does not otherwise support Alcon's position that "native guar" and "hydroxypropyl guar" are subgenera of "guar."

Alcon also cites the Federal Circuit's decision in *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.* for the proposition that it is permissible to list overlapping classes within a Markush group. *Eli Lilly* is distinguishable from the facts of the present case because the court was forced to choose between a construction that violated the doctrine of claim differentiation and one that was redundant. 845 F.3d at 1372 ("[F]aced with an interpretation that would read redundancy into claim 1 and another that would violate the doctrine of claim differentiation, we hold that the claims here support the former result over the latter."). The Federal Circuit determined that the Markush group member could be construed in a manner that would render the term redundant with another Markush group element, noting that a statement in the prosecution history explicitly supported this redundancy. *Id.* at 1371-72. There is no similar statement in the prosecution history of the present case permitting redundancy, and the court is not faced with the circumstance of choosing between competing constructions, either of which would violate a doctrine of claim construction. Instead, Alcon's proposed construction presents an issue of claim differentiation, whereas Watson's proposed construction comports with the fundamental principles of claim construction. Consequently, I recommend that the court adopt Watson's proposed construction.

C. Term 3: "Nepafenac" ('398 patent, claims 1, 13-15, 32)

Alcon's proposal	Watson's proposal	Court
"a known compound having the formula $C_{15}H_{14}N_2O_2$ and having the following structure: 	"3-benzoylphenylacetic acid and certain of its derivatives known to possess anti-inflammatory activity, including amfenac (2-amino-3-benzoylphenylacetic acid) and nepafenac (2-amino-3-benzoylbenzeneacetamide)"	"3-benzoylphenylacetic acid and certain of its derivatives known to possess anti-inflammatory activity, including amfenac (2-amino-3-benzoylphenylacetic acid) and nepafenac (2-amino-3-benzoylbenzeneacetamide)"

I recommend that the Court adopt Watson's proposed construction, which is supported by the intrinsic record. The dispute centers on whether the term "nepafenac" is limited to a single compound, or whether it also embraces other derivatives of 3-benzoylphenylacetic acid. The specification describes nepafenac as follows:

> Nepafenac is a known nonsteroidal anti-inflammatory compound, and can be made by known methods. See, for example U.S. Pat. Nos. 5,475,034 and 4,313,949, the entire contents of which are incorporated by reference. Nepafenac is also known as 2-amino-3-benzoylphenylacetic acid. The topical use of nepafenac and other amide and ester derivatives of 3-benzoylphenylacetic acid to treat ophthalmic inflammation and pain is disclosed in U.S. Pat. No. 5,475,034.

('398 patent, col. 4:49-57)

The parties agree that the ordinary and customary meaning of nepafenac is 2-amino-3-benzoylphenylacetamide,[3] which is generally understood as a single compound ($C_{15}H_{14}N_2O_2$) having the chemical structure as shown in Alcon's proposed construction, and does not include the separate compound amfenac. (D.I. 128, Ex. B at ¶¶ 31-32; D.I. 138 at 17-18). The parties also agree that the ordinary and customary meaning of amfenac is 2-amino-3-

[3] The chemical name for the formula commonly understood to be nepafenac is also known as 2-(2-amino-3-benzoylphenyl)acetamide. (D.I. 129, Ex. 4)

benzoylphenylacetic acid. However, the ordinary and customary meaning for nepafenac is rebutted by the teaching of the '398 patent specification in the present case, which indicates that nepafenac "is also known as 2-amino-3-benzoylphenylacetic acid," despite the fact that this compound is commonly known as amfenanc. ('398 patent, col. 4:49-57)

When a patentee includes a special definition for a claim term in the specification which differs from the meaning it would otherwise possess, the patentee's lexicography governs. *See Phillips*, 415 F.3d at 1316. "To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning." *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1330 (Fed. Cir. 2012) (internal quotation marks omitted). This "clear expression" may be "inferred from clear limiting descriptions of the invention in the specification or prosecution history." *Id.*; *Phillips* , 415 F.3d at 1313 ("Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification."). To achieve lexicography, the specification as a whole must "clearly, deliberately or precisely indicate that the inventors have acted upon their lexicographic license to challenge the meaning" of the disputed claim term. *Alcon, Inc. v. Teva Pharms. USA, Inc.*, 664 F. Supp. 2d 443, 456-57 (D. Del. 2009).

The first two sentences of the specification defining nepafenac extend the term to include a number of other derivatives of 3-benzoylphenylacetic acid, exceeding the boundaries of the formula proposed by Alcon in its proffered construction. The second sentence purports to incorporate by reference into the '398 patent "the entire contents" of U.S. Patent Nos. 5,475,034 ("the '034 patent") and 4,313,949 ("the '949 patent"), which set forth "known methods" of making nepafenac. ('398 patent, col. 4:51-53; 8:54-57) Because Alcon "chose to incorporate by

reference the teachings" of the '949 and '034 patents to define the scope of nepafenac, "these publications are highly relevant to one of ordinary skill in the art for ascertaining the breadth of the claim term." *See AquaTex Indus., Inc. v. Techniche Sols.*, 419 F.3d 1374, 1381 (Fed. Cir. 2005).

The '949 patent, entitled "Method of Producing an Inhibitory Effect on Blood Platelet Aggregation," relates to a family of "novel 2-amino-3-benzoylphenylacetamides" defined by a structural formula. ('949 patent, Abstract; col. 1:10-11; col. 1:44-45; '034 patent, col. 1:26-28) Because the '949 patent does not itself refer to "nepafenac," a person of ordinary skill in the art would follow the "entire contents" instruction of incorporating the known methods claimed in the '949 patent into '398 patent, and would view the recited "2-amino-3-benzoylphenylacetamides" as "example[s]" of nepafenac. ('949 patent, col. 4:56-6:43; 7:1-12:14) The '034 patent, entitled "Topically Administrable Compositions Containing 3-Benzoylphenylacetic Acid Derivatives for Treatment of Ophthalmic Inflammatory Disorders," relates to a family of "novel derivatives of 3-benzoylphenylacetic acid compounds" defined by a different structural formula. ('034 patent, Abstract, col. 2:35-36, 2:51) Absent any reference to "nepafenac," a person of ordinary skill would read the '034 patent in conjunction with the previously-filed '949 patent, which broadly defines "2-amino-3-benzoylphenylacetamide," and would view all of the recited derivatives of 3-benzoylphenylacetic acid as additional examples of nepafenac. ('034 patent, col. 7:25-12:48, 13:1-20) Although incorporation by reference of the '034 and '949 patents does not expressly "impart a novel meaning" to nepafenac in the '398 patent specification, "the written description of the preferred embodiments can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format." *Bell Atl. Network*

Servs., Inc. v. Covad Commc'ns Grp., Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001) (internal citations and quotation marks omitted).

The third sentence of the paragraph defining nepafenac in the '398 patent specification states that "[n]epafenac is also known as 2-amino-3-benzoylphenylacetic acid." ('398 patent, col. 7:37-38) This sentence expressly extends the definition of nepafenac beyond its commonly-understood meaning to specifically include 2-amino-3-benzoylphenylacetic acid. *See AstraZeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharm. Co., Inc.*, 384 F.3d 1333, 1339 (Fed. Cir. 2004) (concluding that "rigid formalism is not required" for a patentee to act as his own lexicographer, and lexicography does not require a statement in the form "I define ____ to mean ____."). Watson's proposed construction is also consistent with the fourth sentence. While "the topical use" of nepafenac "is disclosed in [the '034 patent]," "known methods" of making "nepafenac" are disclosed in both the '949 and '034 patents. ('398 patent, col. 4:49-57)

Contrary to Alcon's contention, Watson's proposed construction draws support from the entire definitional paragraph describing "nepafenac" rather than a single sentence in the specification. Alcon's proposed construction is directly contradicted by each of the first three sentences for the reasons previously stated. Alcon's assertion that the third sentence constitutes an error lacks support in the intrinsic record, as the asserted error is "not evident from the face of the patent itself," nor is it "clearly evident from the specification, drawings, and prosecution history how the error should appropriately be corrected." *See Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1356-57 (Fed. Cir. 2003).

Watson's proposed construction is also consistent with the rest of the specification. The use of amfenac in Examples 3 and 4 does not negate the broad scope of nepafenac because the specification defines amfenac functionally in relation to nepafenac as its metabolic precursor.

('398 patent, col. 7:35-60) Reciting specific examples of post-metabolic amfenac does not impose limitations on pre-metabolic nepafenac. While nepafenac, as referred to in claim 1, relates to "[a] topically administrable aqueous ophthalmic suspension composition" before administration to patients, ('398 patent, claim 1; col. 4:43-44), Examples 3 and 4 are focused on the anti-inflammatory effects of the claimed compositions by comparing the post-metabolic profiles of nepafenac "in the rabbit iris ciliary body," ('398 patent, col. 7:43-45; col. 8:1-7). Nor does the reference to NEVANAC® negate the broad scope of "nepafenac." Although the NEVANAC® labeling narrows the "nepafenac" in Example 3 to the single compound 2-amino-3-benzoylphenylacetamide, ('398 patent, col. 7:39-48), the specification cautions against reading individual embodiments to limit the scope of nepafenac. ('398 patent, col. 8:43-50) ("[T]he scope of the present invention is not intended to be limited to the particular embodiments of any process, manufacture, composition of matter, compounds, means, methods, and/or steps described in the specification. Various modifications, substitutions, and variations can be made to the disclosed material without departing from the spirit and/or essential characteristics of the present invention.")

The intrinsic record establishes that the patentee of the '398 patent chose to define nepafenac so as to broaden the scope of the term beyond its ordinary meaning. (11/1/17 Tr. at 71:13-17) "[A] definition of a claim term in the specification will prevail over a term's ordinary meaning if the patentee has acted as his own lexicographer and clearly set forth a different definition." *See 3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371 (Fed. Cir. 2003); *see also Vitronics Corp.*, 90 F.3d at 1582 ("The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.").

For the foregoing reasons, I recommend that the court adopt Watson's proposed construction of "nepafenac."

V. CONCLUSION

For the reasons set forth above, I recommend the disputed terms be construed as follows:

Claim Term	**Recommended Construction**
"native guar" ('398 patent, claims 1, 13-14, 21, 32)	Indefinite
"a galactomannan at a concentration of 0.1 to 0.4 w/v %, said galactomannan selected from the group consisting of guar, native guar, and hydroxypropyl guar" ('398 patent, claim 1)	"only one, single galactomannan that is guar or native guar or hydroxypropyl guar, and not mixtures or combinations thereof, at a concentration of 0.1 to 0.4 w/v %"
"nepafenac" ('398 patent, claims 1, 13-15, 32)	"3-benzoylphenylacetic acid and certain of its derivatives known to possess anti-inflammatory activity, including amfenac (2-amino-3-benzoylphenylacetic acid) and nepafenac (2-amino-3-benzoylbenzeneacetamide)"

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. Appx. 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

Given that the court has relied upon material that technically remains under seal, the court is releasing this Report and Recommendation under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Report and Recommendation should be redacted, the parties should jointly submit a proposed redacted

version by no later than **December 15, 2017**. The court will subsequently issue a publicly available version of its Report and Recommendation.

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, http://www.ded.uscourts.gov.

Dated: November 30, 2017

Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE